PRODUCT MANUAL FOR
Medical Textiles — Surgical Face Masks
According to IS 16289:2014

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	**Product**	:	IS 16289:2014
	Title	:	Medical Textiles — Surgical Face Masks
	No. of Amendments	:	0
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	No specific requirement
b)	**Grouping guidelines**	:	Please refer ANNEX –A
c)	**Sample Size**	:	30 pieces
3.	**List of Test Equipment**	:	Please refer ANNEX –B
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX –C
5.	**Possible tests in a day :**		
	Since testing facility is not available in any BIS/BIS recognized lab, complete testing has to be carried out in the Factory for considering certification on FT basis, **4 days** required for complete testing.		
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 16289:2014 with the following scope:		

	Name of the product	Medical Textiles — Surgical Face Masks
	Class	Class 1/Class 2/ Class 3

ANNEX A
Grouping Guidelines

IS 16289:2014 covers three classes of face masks based on performance

- Class 1
- Class 2
- Class 3

If a sample of Class 3 is drawn and tested, Classes 1,2 and 3 can be considered for grant of licence/addition in scope on that basis. Similarly, if Class 2 sample is drawn and tested, Classes 1 and 2 can be considered for grant of licence/addition in scope. However, if Class 1 sample is tested, Class 1 may only be considered for for grant of licence/addition in scope

However, it shall be ensured that the firm has the requisite manufacturing and testing facilities to produce the varieties intended to be covered in the scope of licence

During operation of licence, samples of all varieties shall be drawn and tested by rotation.

ANNEX B
List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Bacterial filtration efficiency Cl 4.2 Table 1 Sl No (i)	**Apparatus:** • Autoclave, capable of maintaining temperature of 121-123 °C. • Incubator, capable of maintaining temperature of 37 + 2 °C. • Analytical Balance capable of weighing 0.001 g • Vortex Mixer, capable of mixing the contents of 16 mm × 150 mm test tubes • Orbital Shaker, capable of achieving 100 - 250 rev/min. • Refrigerator, capable of maintaining 2-8 °C. • Six stage viable particle cascade impactor • Vacuum Pump, capable of 57 litre/min • Air Pump/Compressor, capable of 1.1 kg/cm2. • Peristatic Pump, capable of delivering 0.01 ml/min • Nebulizer, capable of delivering mean particle size of 3.0 micrometer and a challenge level of 2 200 particles per test • Glass Aerosol Chamber, 60 cm × 8 cm diameter tube. • Colony Counter, manual or automatic, capable of counting upto 400 colonies per plate • Automatic Pipetor, capable of delivering 1.0 + 0.05 ml • Flow Meters, capable of 28.3 litres/min. • Pressure Gauges, capable of 35 + 1 kPa • Air Regulator **Reagents:** • Staphylococcus Aureus, ATCC#6358 • Tryptic soy Agar (TSA) 6 • Tryptic soy broth (TSB) 6 • Peptone Water *Test method reference : IS 16288:2014*

2	Differential Pressure Cl 4.2 Table 1 Sl No (ii)	Apparatus for measuring air resistance with a Flow Meter, capable of measuring an air flow of 8 litre/min, Manometers, Electric Vacuum Pump and Needle valve *Test method reference: Annex C of IS 16289:2014*
3	Splash resistance Cl 4.2 Table 1 Sl No (iii)	• **Splash resistance test apparatus**: A suitable test apparatus to dispense a specified volume of synthetic blood through a small diametercanula (1.27 cm long with an internal diameter of 0.084 cm and length more than 30.5cm) over a controlled amount of time at aspecimen mask a set distance away. The test apparatusconsists of a specimen holding fixture, a targetingplate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable canula and a valve controller. The test apparatus includes a base for more convenient mounting of the components anda hood or other components to contain or control the splash. • **Synthetic Blood** • **Isopropanol**, laboratory grade, for cleaning the apparatus. • Talcum Powder, Pipette capable of dispensing 0.1 ml , Stop Watch *Test method reference: Annex D of IS 16289:2014*
4	Sub-micron particulate filtration efficiency	Aerosol test system consisting of clean, dry compressed air supply, HEPA filters, aerosol generator, charge neutralizer, humidifier, test filter holder and duct assembly, pressure drop measuring device, air flow rate measuring device, temperature and humidity detectors and optical particle counters, Latex Suspension, Oscilloscope. *Test method reference: Annex E of IS 16289:2014*
5	Conditioning	Conditioning chamber to condition at 21 ± 5 °C, 85 ± 5% RH for test at Sl No 1 and at 27 ± 2 °C, 65 ± 2% RH for tests at Sl No 3 and 4 Barometer

Note: The above list is indicative only and may not be treated as exhaustive.

ANNEXURE-C

SCHEME OF INSPECTION AND TESTING
FOR Medical Textiles — Surgical Face Masks
ACCORDING TO IS 16289:2014

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

The manufacturer shall prepare a calibration plan for the test equipment.

2. TEST RECORDS –The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. PACKING AND MARKING– The Standard Mark as given in the schedule of the licence shall be indelibly marked on the mask and its packages along with the other marking details as required by the standard. Packing and Marking shall be done as per the provisions of the Indian Standard. The following shall be marked in (addition –

a) The BIS licence number
b) The phrase 'Please see www.bis.gov.in for BIS certification details'. *
**In case of space constraints, (b) may be marked only on the package*

4. TEST CERTIFICATE– Each consignment of surgical face masks shall be supplied with a certificate to the effect that the units being supplied have been tested as per the requirements of the specification and found suitable for use.

5. CONTROL UNIT – For the purpose of this scheme, all surgical masks of the same class and produced in one day shall be considered as a control unit.

6. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2above.

6.1 All the production which conforms to the Indian Standard and covered by the licence should be marked with Standard Mark.

7. REJECTIONS–Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016.

TABLE 1
LEVELS OF CONTROL

Test Details (1)				(2)	Levels of Control (3)		
Cl.	**Requirement**	**Test Methods**		**Test equipment requirement R: required (or)S: Sub-contracting permitted**	**No. of Samples**	**Frequency**	**Remarks**
		Clause	**Reference**				
4.1	Materials, construction and Design	4.1	IS 16288	S	Based on lot size as per column 3 of Table 2 of IS 16289	Every 7th control unit	
4.2	Bacterial Filtration Efficiency	4.2	IS 16288	S	5	Each 15th control unit	
-do-	Differential Pressure	Annex C	IS 16289	S	5	Every 7th control unit	
-do-	Splash Resistance	Annex D	-do-	S	5	-do-	
-do-	Sub-micron particulate filtration efficiency at 0.1 µ	Annex E	-do-	S	5	-do-	

Note 1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau

Note 2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification to BO head.